

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAID DRUG USE REVIEW
PROGRAMS**

LESSONS LEARNED BY STATES



JUNE GIBBS BROWN
Inspector General

MAY 1995
OEI-01-92-00800

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This report was prepared under the direction of Mark R. Yessian, Ph.D., Regional Inspector General, and Martha B. Kvaal, Deputy Regional Inspector General, Boston Region, Office of Evaluation and Inspections. Participating in this project were the following people:

Boston Region

Barry McCoy
Craig Schneider

Headquarters

Mary Beth Clarke

For additional copies of this report, please contact the Boston regional office by telephone at (617) 565-1050 or by fax at (617) 565-3751.

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EXECUTIVE SUMMARY

PURPOSE

This study identifies lessons the States have learned in implementing the Medicaid drug use review requirements established by Congress in 1990.

BACKGROUND

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) requires State Medicaid agencies to implement comprehensive drug use review (DUR) programs to improve the quality and cost-effectiveness of drug therapies. Drug use review is a process for identifying (1) potential safety problems with prescriptions, prospectively, at the time of dispensing and (2) questionable patterns of prescribing and/or dispensing problems retrospectively through reviews of prescription claims data. The third component of drug use review is programs for educating physicians and pharmacists about appropriate drug therapies.

This report begins by identifying nine important lessons learned by States as they have developed and implemented DUR programs. Each lesson includes vignettes that specify ways in which some States have applied the lesson. We include those that seem to be sufficiently different and important to warrant the attention of other States. This report concludes with discussion of several challenges that, if not addressed, could undermine States' DUR efforts in the years ahead.

We drew on three major sources of information for the lessons, vignettes, and issues discussed in this report: the literature on drug use review; discussions with many State and Federal DUR officials and review of their internal documents; and on-site visits to DUR programs in six States.

LESSONS LEARNED BY STATES

Lesson 1: Develop credible drug use criteria.

Credible criteria provide an essential foundation for DUR programs. Physicians and pharmacists must have confidence that the criteria are based on professional expertise, prior experience, and up-to-date, science-based research. States could:

- ▶ establish guidelines for the States' drug use review boards to use when reviewing criteria; and
- ▶ obtain feedback on criteria from many sources.

Lesson 2: Be selective in developing and applying drug use criteria.

States' review of the voluminous pharmacy claims can easily generate extensive data and result in information overload. Reviews need to be selective. States could:

- ▶ focus criteria on clinically important areas; and
- ▶ apply only a few criteria at one time.

Lesson 3: Apply drug use criteria with a high degree of specificity.

States also risk information overload if their criteria are too broadly defined. Highly specific criteria can reduce the number of less significant alerts. States could:

- ▶ modify or eliminate criteria after reviewing the volume of alerts; and
- ▶ conduct careful pilot tests of the criteria before implementation.

Lesson 4: Examine patterns of drug use, prescribing, and dispensing.

Pattern analysis can be valuable for identifying those providers and patients warranting intervention and in maximizing the effectiveness of the DUR effort. States could:

- ▶ establish relational data bases to give a broad picture of drug use; and
- ▶ develop profiles of drug use for patients, physicians, and pharmacies.

Lesson 5: Present data in ways that facilitate analysis and corrective action.

To be useful, the basic data generated by DUR reviews must be presented to program officials and to the providers in ways that are easily understood. States could:

- ▶ display data for providers that compares them with their peers; and
- ▶ report performance data in context.

Lesson 6: Intervene with providers having questionable prescribing and dispensing practices in ways that motivate change.

The DUR programs need to intervene in ways that are feasible yet effective in influencing providers' drug therapy practices. States could:

- ▶ tailor intervention letters to the individual and include credible and compelling information; and
- ▶ invest selectively in personal contacts with providers.

Lesson 7: Foster compliance with patient counseling requirements.

Counseling patients about their drug therapy is important in encouraging appropriate drug use. Yet pharmacists confront many obstacles to counseling, and States have difficulty monitoring pharmacists' compliance with the law. States could:

- ▶ use pharmacy inspectors as patients to assess compliance;
- ▶ survey pharmacists and patients by mail; and
- ▶ take punitive actions when necessary.

Lesson 8: Educate physicians and pharmacists proactively about appropriate prescribing and dispensing practices.

States emphasize the educational nature of DUR programs and promote this message with providers having questionable practices. But States can also adopt preventive approaches by educating the larger provider community. States could:

- ▶ mail special messages to all providers;
- ▶ target special training to specific provider groups; and
- ▶ use the information superhighway.

Lesson 9: Establish on-going research efforts to help guide the program.

States rely on a limited knowledge base to guide them. Applied research efforts can be important for helping DUR programs operate efficiently and effectively. States could:

- ▶ evaluate their screening criteria;
- ▶ examine sources of alerts by practice setting and location; and
- ▶ assess effectiveness of different types of educational interventions.

MAJOR CHALLENGES FACING STATE DUR PROGRAMS

States have been moving ahead with their DUR programs through largely uncharted territory. They have crafted many different approaches to DUR and have learned from their experience. At the same time, DUR programs face several challenges, which, if not adequately addressed by State and Federal leadership, could undermine the effectiveness of their efforts in the years ahead.

Privacy safeguards.

- ▶ *Do the programs give adequate attention to privacy safeguards?*

The widespread use of large, automated systems for reviewing Medicaid beneficiaries medical and drug histories raises important privacy issues concerning what data should be collected and who should have access to these data and under what conditions.

Protection of poor performers.

- ▶ *Does the educational focus of the programs unnecessarily inhibit efforts to protect beneficiaries from poorly performing providers?*

State DUR programs emphasize educational approaches for improving providers' prescribing and dispensing practices; they rarely pursue punitive actions. The DUR programs appear to lack interventions, falling in the middle of this continuum, that could help in situations in which a provider's knowledge base or practice skills raise serious questions yet do not warrant referral for possible disciplinary action.

Education of patients.

- ▶ *Are the programs sufficiently focused on patient education?*

State DUR programs focus almost exclusively on educating physicians and pharmacists. Helping patients become better informed about their drug therapies receives very little emphasis, even though the health care system is being transformed by the growing influence of patients in decision making about their medical care.

Dependence on vendors.

- ▶ *Are the programs too dependent on the vendors serving them?*

Most frequently, States rely on vendors to provide the screening criteria, the computer software, and other technical know-how essential to DUR efforts. This expertise has been invaluable to DUR programs; yet the heavy reliance on vendors raises issues about whether States have enough expertise in-house to ensure that the vendors' work meets the States' own particular needs.

Problems with Medicaid claims data.

- ▶ *Do inaccurate, incomplete Medicaid claims data bases serve as a significant constraint to the programs?*

Problems with incomplete and/or inaccurate data surfaced in virtually every State we contacted. They can make it difficult for DUR programs to be efficient and effective.

Validity of cost-savings estimates.

- ▶ *Are the programs claiming cost savings that rest on weak foundations?*

Estimating cost savings for DUR programs is essential but highly complex and resource-intensive. The HCFA has been developing guidelines to help the States prepare meaningful estimates. Yet the situation remains one in which the estimates can be misleading about the impact of the DUR programs.

Balance between cost and quality.

- ▶ *Are the cost-saving and quality-of-care objectives of the programs in balance?*

Both objectives are vital to DUR programs. Yet given the cost pressures and the complexity of decisions around criteria, screens, and interventions, States face significant challenges in ensuring that the programs, in fact, balance both objectives.

Implications of managed care.

- ▶ *Are States developing a DUR infrastructure that will become increasingly irrelevant as Medicaid managed care enrollment escalates?*

Thus far, State DUR programs have given little attention to this significant change. Yet the implications for them are profound. Medicaid beneficiaries who enroll in these plans, many of which provide prescription drug coverage, become the responsibility of the plans. Their drug use, and the prescribing and dispensing practices of their health care providers are then, in effect, beyond the reach of the States' DUR efforts.

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INTRODUCTION

PURPOSE

This study identifies lessons the States have learned in implementing the Medicaid drug use review requirements established by Congress in 1990.

BACKGROUND

State Medicaid programs have been reviewing the outpatient drug use of Medicaid beneficiaries for many years. These efforts, while particularly useful in identifying fraud and other illegal activities, have been piecemeal and incremental. In 1990, the Omnibus Budget Reconciliation Act (OBRA 90) changed the picture considerably.¹ It required States to take a much more ambitious approach to Medicaid drug use review (DUR) to ensure better patient care through drug therapies that are appropriate, necessary, and cost effective. Specifically, it required States to implement, by January 1993, programs for:

- ▶ *prospective drug use review (pro-DUR)* and counseling by the pharmacist that occur before each prescription is dispensed to help ensure appropriate drug therapy for the patient;
- ▶ *retrospective drug use review (retro-DUR)* of pharmacy claims data that identify patterns of physician prescribing, pharmacist dispensing, and patient drug use that may be inappropriate; and
- ▶ *educational outreach* that educate providers about appropriate drug therapies.

The pro- and retro-DUR reviews are guided by criteria and standards adopted by States as benchmarks for determining the appropriateness of drug therapies for particular conditions. Prescription claims are screened against these benchmarks. State DUR boards, composed primarily of physicians and pharmacists, have broad responsibility for reviewing drug review criteria, for guiding the reviews, and for directing interventions and other educational efforts with pharmacists and physicians.

The States have faced many challenges as they have struggled with mounting their DUR programs. They have learned some important lessons along the way. No one State, it seems to us, serves as a model for how to implement a program from beginning to end. Yet, we and HCFA's Medicaid Bureau, with whom we collaborated in designing this study, think some of the lessons learned by the States can be instructive to other States. In this report, we focus on these lessons. We intend it to serve as a resource document offering vignettes of some States' experiences so far. Although it is not a definitive assessment of what does or does not work, we expect the report can help States learn from each others' experiences and can contribute to their developing effective DUR programs. We have geared the report not to the technical specialists, but to those State

administrators, legislators, board members, and others who deal with DUR policies more generally. For this reason, we avoid detailed discussion of the technicalities of the review process.

We begin this report by identifying nine major lessons that have been important in the States' early implementation efforts. Some lessons apply to both prospective and retrospective components of a DUR program; some are more applicable to one than the other. All are experiences that States described to us or to HCFA; some approaches may, in fact, no longer be used. We begin each lesson with a brief introduction that highlights its importance for the States' overall DUR efforts. Then, for each lesson, we present selected vignettes that specify ways in which States have applied the lesson. We conclude the report by discussing several unresolved issues that, if left unresolved, could undermine States' DUR programs in the years ahead.

METHODOLOGY AND DEFINITIONS

We relied on three major sources of information for this report:

- ▶ an examination of the literature on drug use review, including pertinent research studies, and relevant government documents such as the OBRA 90 legislation, its regulations, and States' own internal reports and their annual reports to HCFA;
- ▶ discussions with many State and Federal DUR officials, including participation in three national meetings of State Medicaid DUR program staff; and
- ▶ on-site visits to DUR programs in six States: Colorado, Illinois, Iowa, Maryland, Massachusetts, and Washington.

The vignettes included here are ones that appear to have potential in multiple States, although we recognize that what works well in one State may not work so well in another. The criteria we used in selecting the vignettes were rigorous yet inherently qualitative. They included: (1) the judgments of the Federal and State officials with whom we conversed; (2) our own review of States' experiences and their supportive materials; (3) our consultation with experts having substantial experience with DUR efforts; and (4) our own judgment of whether a particular approach or item is sufficiently different and important to warrant the attention of other States based on our own considerable experience over many years in studying pharmacy issues.²

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

MEDICAID DRUG USE REVIEW: THE BASICS

Drug use review is a process for examining the use of prescription drugs. Its purposes are twofold: (1) It helps ensure the quality of Medicaid beneficiaries' health care through improved drug therapies, and (2) it helps generate cost savings by reducing illnesses related to adverse drug reactions and by encouraging use of lower cost drugs. Thus States review prescriptions for appropriateness, medical necessity, and cost effectiveness of the therapy. They also review them to identify fraud, waste, and abuse.

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) requires prescriptions be reviewed (or "screened") against predetermined criteria and standards.* These reviews identify possible problems such as therapeutic duplications, drug-disease contraindications, incorrect dosages, and drug-drug interactions. When the screens identify potential problems with a particular prescription or drug therapy, States may choose to take action.

Drug use review has two distinct components: prospective review (referred to as pro-DUR) and retrospective DUR (referred to as retro-DUR).

Prospective DUR occurs before a prescription is filled. A pharmacist uses her/his professional judgment about the appropriateness of the prescription and may consult authoritative sources, either manually or electronically, when performing this initial review. The pharmacist may then discuss potential problems with the beneficiary or the physician. As part of this pro-DUR process, the pharmacist must offer counseling, consistent with State requirements, to beneficiaries about their drug therapy.

The OBRA 90 encourages States to implement prospective DUR using Statewide, on-line automated systems that are integrated with other automated claims processing systems such as the Medicaid Management Information Systems (MMIS). Pro-DUR programs that use a statewide, on-line system can be particularly effective because it allows profiling of physicians' and pharmacists' prescribing and dispensing practices. It also allows prescriptions to be screened against beneficiaries' complete drug and medical histories. These histories may involve multiple physicians and pharmacies. At least 21 States are now operating on-line pro-DUR systems; many others are planning to do so.

With on-line pro-DUR systems, pharmacists submit claims electronically at the time of dispensing. The claims are screened to check various administrative requirements, such as eligibility. They are also screened against the States' DUR criteria. This screening may generate alerts (or exceptions). Most alerts flag potential drug therapy problems for the pharmacists; far fewer alerts are for administrative purposes such as denial of payment.

Retrospective DUR occurs after a prescription has been filled and the claim submitted for payment. It involves reviews of large numbers of claims at least quarterly and uses the States' automated systems for claims processing, such as the MMIS. As with automated on-line pro-DUR, claims are screened using computerized algorithms based on the DUR criteria, and the system generates alerts to flag potential problems. In particular instances of questionable drug therapy, States may decide to communicate with the beneficiary, the pharmacist, or the physician in an effort to change their behaviors. Most often, they write letters to physicians and pharmacists. Far less often, they refer problems with the potential for disciplinary action to other State agencies.

** NOTE: In the OBRA 90 regulations, the Health Care Financing Administration distinguishes criteria from standards. It refers to criteria as norms for health care that reflect the expertise and experience of health professionals and the professional literature. It defines standards as the expressions of acceptable variation from the norm or criterion. We learned that DUR officials commonly use the "criteria" when referring to the criteria or to the standards. It is in this broader sense that we, too, use the term "criteria" in this report.*

LESSONS LEARNED BY STATES

LESSON 1: DEVELOP CREDIBLE DRUG USE CRITERIA

Credible criteria provide an essential foundation to an effective drug use review program. Physicians and pharmacists must have confidence that they are based on professional expertise, prior experience, and up-to-date science-based research.³ Otherwise, the rationale for the effort is likely to be questioned and compliance undermined.

- ▶ **Establishing Guidelines for a DUR Board.** State DUR boards provide a vital focal point for ensuring that criteria used in pro- and retro- DUR efforts are credible. Many of the boards have become active in assessing the appropriateness of the criteria developed by vendors. Colorado facilitated such an assessment by developing a checklist for DUR board members to use in reviewing criteria (see box).

CHECKLIST FOR REVIEWING DUR CRITERIA

Among the questions posed in Colorado's checklist are the following:

- Who developed the criteria? Did they get outside review from practicing physicians and pharmacists?
- How adequate is the literature review? What are their sources? Did they look for unlabeled uses supported by scientific literature?
- How adequately is the literature interpreted? What is the quality of the evidence? Did they choose the most or least restrictive interpretation? Did they look for efficacy or cost-effectiveness studies? Did they consider the population limits of particular studies?
- If a drug group is used for many clinical subsets, are they explicit about the domain of the criteria for each subset? If a subset has different dosage or duration recommendations for use of a drug, is this addressed in each criteria?
- For drug interactions, are the definitions for "interaction" and "clinical significance" clear? Do they note the dosages at which interactions have been documented? Do they consider the sequence of using the drugs?
- Can use of the criteria set assist reviewers in suggesting appropriate therapy? Other drugs, therapeutic maneuvers, and/or other therapeutic modalities?

- ▶ **Obtaining Feedback on Criteria.** An open process allowing widespread participation can pay big dividends. It can provide a DUR program with valuable insights in developing criteria. It can also foster broad acceptance of the resulting decisions. Many boards have moved in this direction by seeking and drawing on the advice of professional associations, medical and pharmacy schools, drug manufacturers, and individual experts in clinical areas under consideration.

The process, moreover, can be constructively viewed as a continuing one, involving feedback not only in developing criteria, but also in reevaluating them over time. The Texas program offers a good case in point. It modified its criteria on the concurrent use of two antidepressant drugs after taking into account physician responses to its intervention letters. In those responses, physicians whose drug use practices were being questioned complained that the maximum dosage levels allowed by the State were too low. After consulting with experts, the DUR program officials agreed and allowed for higher dosages that were more consistent with current thinking about appropriate dosage levels.

Obtaining feedback on criteria, whether at the outset or after implementation, is no less important for DUR criteria directed to pro-DUR than to those concerning retro-DUR. This is important to note because pro-DUR criteria often have been applied all at once, with little review and testing and with refinements made only after numerous provider complaints.

- ▶ **Facilitating Feedback through a Ballot Process.** The Virginia program used a mailed ballot to facilitate reviews by the DUR board as well as by medical and pharmacy associations, schools, and drug manufacturers. The reviewers received a draft set of criteria for comment together with a preprinted form with check boxes for responding to questions and selecting options. The form also included room for reviewers to provide narrative comments. Shortly thereafter, reviewers received a second ballot of the revised criteria. These became the official criteria if no other comments were offered. This check box, ballot approach, program officials reported, contributed to more consistent and thorough feedback and to easier synthesis and analysis of reviewer comments.

LESSON 2: BE SELECTIVE IN DEVELOPING AND APPLYING DRUG USE CRITERIA.

Without careful planning, DUR programs can easily result in information overload. Their review of pharmacy claims can generate extensive data that severely taxes the limited resources of the program and the good will of the practicing physicians and pharmacists. Some States run monthly screens on all their criteria and produce exceptions far exceeding those that they can address. An antidote to such a condition is to gear the program to relatively few drug use criteria in clinically important areas. This applies to both on-line prospective DUR efforts and to retrospective efforts. It is particularly important for retrospective efforts, which seek to identify problems after the fact and which call for follow-up by program staff, to pursue a more selective approach to applying established criteria in order to avoid the forementioned consequences of information overload.

- ▶ **Focusing on Clinically Important Areas.** What bases are to be relied upon in defining "clinically important areas?" Wisconsin, in developing about 20 retrospective criteria, used the following bases to guide its decisions: (1) indications in the clinical literature of frequent misutilization, (2) likelihood of misutilization having a significant impact on quality of care, and (3) likelihood of it having a major impact on Medicaid expenditures.

Colorado, in developing the eight topics or "modules" that guided its retrospective effort, took a somewhat different approach. It, too, addressed cost concerns by focusing on drugs that represent a disproportionate share of Medicaid pharmacy costs. But in addressing quality concerns, it focused on drugs with high potential for toxicity and on the use of medications in high-risk populations. The latter included drugs taken by pregnant women and neuroleptic drugs taken by the elderly.

- ▶ **Screening Paid Claims Strategically.** Among the approximately 20 criteria developed by Wisconsin, it selected 1 to 3 each month for screening against paid claims. The State took this approach because it wanted to limit the alerts identified through the screening process to those it could reasonably expect to follow up with intervention letters to the providers. With a manageable number of alerts, it was also able to produce intervention letters that were tailored to the potential inappropriate drug use identified.

Colorado followed much the same approach, with a similar rationale. In its screening of paid claims, it rotated among its eight established modules (a ninth was added recently). This meant that it was highly unlikely that any one module (for example, drugs in pregnancy) would be applied more than once in a year and might well not be applied for close to 2 years.

Washington's intent to conduct its retrospective reviews strategically led it to develop what it has called the "onion" approach. Through this approach, the program would start out by identifying the "onion"--a significant therapeutic concern based on analysis of claims data that surfaces drugs of high risk, high cost, and/or high use. Subsequently, and gradually, the program narrows the focus of its analysis by identifying particular layers of the onion for further screening and review (see box).

THE "ONION" APPROACH:

HIGH-COST ANTIBIOTIC SUSPENSIONS

Through their screening efforts, Washington officials identified high-cost antibiotic suspensions as among the most frequently prescribed and most expensive drugs paid for by the Medicaid program. Upon further review, they found that these drugs were being used frequently for treating otitis media (middle ear infection) in children. This practice raised questions because the State's DUR criteria ranked these suspensions as the third drug of choice for these children. This led to further screening to identify the dimensions of the problem--in particular, to identify the physicians writing prescriptions for the suspensions, their patient caseloads, and the volume and type of prescriptions they wrote. These data formed the basis for subsequent analysis of prescribing patterns and of patient drug use.

LESSON 3: APPLY DRUG USE CRITERIA WITH A HIGH DEGREE OF SPECIFICITY.

Being selective in choosing and applying criteria is essential, but in itself insufficient in averting the dangers of information overload. If States fail to incorporate highly specific problem definitions into the computer algorithms they use to screen claims, they are quite likely to generate many false positives and many more alerts than they or providers can reasonably address. Indeed, experience has shown this to be the case in States that use broadly inclusive definitions (highly sensitive) in their screening criteria. In one such State, the on-line prospective DUR system has been identifying alerts at the rate of 20 percent. This means that one out of every five electronic claims that pharmacists submit result in an immediate computerized alert suggesting a possible problem with the prescription. In another State, the retrospective DUR system has been generating 50,000 alerts a month. Of these, the program has been randomly selecting 1,500 to 2,000 for review to determine if the providers should be contacted.

- ▶ **Reducing the Number of Unnecessary On-Line Prospective DUR Alerts.** During the early period of its on-line system, Pennsylvania was experiencing an alert rate of about 20 percent. Too many of these alerts were suspected to be false positives. After verifying some of the alerts as being false positives, the State took action to make the alerts more meaningful and to reduce the number of alerts to a more manageable level (about 10 percent) (see box).

EFFORTS TO REDUCE PRO-DUR ALERTS

Pennsylvania modified its screening criteria in three areas:

- Claims for children were often triggering minimum dose alerts. Upon inquiry, the State found that the low-dose edits, which had been developed for adults, were being applied to children. It decided to bypass them for children's prescriptions.
- The minimum/maximum dosage screens for topical medications, such as ointments, were generating many false positive-alerts. The State dropped them in these instances because they were irrelevant.
- The computerized algorithm concerning therapeutic duplication for psychotherapeutic drugs was generating too many unnecessary alerts. The State tightened the problem definition so that alerts have been generated only if the prescriptions involve different pharmacies or different physicians.

Virginia contributed to a reduction of DUR alerts by deleting all the low-dose edits and by keying alerts on drug-drug interactions to only the two most serious levels of clinical significance identified in the criteria.

Illinois also eliminated low-dose edits as a way of removing clinically insignificant information from its system and of reducing its prospective DUR alert rate. It found that such edits were often being triggered by the common, acceptable prophylactic use of antibiotics 1 or 2 days before a surgical or dental procedure.

Texas sought to avoid the start-up problems other States have experienced with their on-line systems by conducting extensive pilot testing to ensure that the alerts generated by its system were significant ones. It involved nearly 80 pharmacies in this effort.

- ▶ **Containing the Number of Retrospective DUR Alerts.** In actuality, a high-specificity approach is one that will tend to give a physician the benefit of the doubt in borderline cases. For example, as a representative of the Colorado program noted, this might mean that in cases where a blood level might ideally be monitored within 2 weeks of starting a drug, the screening criterion might allow a month to go by before generating an alert.

In the same context, Wisconsin, once it identified alerts concerning its criterion for H2 antagonists (a class of drugs for treating ulcers), would not send an intervention letter to a provider unless he/she had alerts generated for at least three patients during the 6-month review period. In its FY 1993 annual report, it elaborated that such a threshold was "established to identify potential patterns of drug use practices, improve the cost-effectiveness of the intervention and reduce practitioner and pharmacist aggravation caused by frequent receipt of DUR letters."

- ▶ **Relying on the Computer to Trigger Intervention Letters.** Applying criteria with a high degree of specificity can minimize the need for a review panel to review each alert to determine if an intervention letter should be sent. But we found only one State, Wisconsin, that actually eliminated that review. Except for a brief administrative review to identify any programming errors, it relied on the computer to identify the alerts and the interventions. The rationale was that this approach reduces the subjectivity associated with manual reviews and minimizes the lag time between identification of alerts and intervention with the provider.

LESSON 4: EXAMINE PATTERNS OF DRUG USE, PRESCRIBING, AND DISPENSING.

A DUR program offers a prime opportunity to identify patterns of questionable practices, be it by patients or by providers. Through retrospective reviews, which can draw on paid claims data as well as on the record of computerized alerts generated by prospective on-line review systems, a State can examine drug use longitudinally. It can profile the drug use practices of patients, encompassing the various physicians and/or pharmacies they visit and encompassing various drug use categories and/or disease states. It can also profile the prescribing practices of physicians and the dispensing practices of pharmacies, focusing on patients served over a period of time and on various drug categories and/or disease states. The information obtained through such pattern analysis can be of major value in directing interventions to providers or patients warranting serious attention. And, not least of all, it can offer compelling evidence of the need for such attention.

- ▶ **Establishing a Broad Relational Data Base.** A necessary starting point for useful pattern analysis is establishing a sufficiently inclusive data base that links key data elements. Colorado, for instance, has developed a relational DUR data base that incorporates information on diagnosis, procedure, hospital stay, patient demography and history, prior authorization request, provider, and, most recently, Medicare crossover data.

Illinois has incorporated into its medical history file of Medicaid beneficiaries the alert information generated from its on-line prospective DUR system. This adds to the retrospective program valuable additional information in profiling not only prescribing practices but also dispensing practices.

- ▶ **Developing Patient Profiles.** This is the most common type of pattern analysis conducted by State DUR programs. It serves to identify patients who may be experiencing drug therapy problems due to their visiting multiple physicians and/or pharmacies. More often, it serves to identify individual physicians who may be prescribing inappropriately.

Massachusetts has found it helpful to append a detailed patient history profile to the intervention letters it sends to physicians. For instance, in a recent letter to a physician, it identified two drugs that the physician had prescribed for a patient on a chronic basis, contrary to standard practice to use them on a short-term basis. The attached two-page patient profile identified all drugs prescribed for the patient over a period of about 14 months; the strength, quantity, and days-to-refill for each drug; the pharmacies and physicians involved; and the various diagnoses made. Easy-to-read summary information highlighted the two interacting drugs and indicated that, in the review period, the patient had seen two physicians and used five pharmacies.

- ▶ **Developing Provider Profiles.** Washington's initiative on high-cost antibiotic suspensions focused on the development of physician profiles. The State screened claims to identify physicians prescribing the high-cost antibiotic for children who were younger than 8 years of age and who had a diagnosis of otitis media; to determine the volume and range of the antibiotics these physicians prescribed for this diagnosis; and to identify the geographic location of their practices. Once it aggregated these data, it revealed the following patterns:
 - Forty-five percent of the prescriptions for these high-cost drugs were written by 124 (6 percent) of those physicians prescribing;
 - Of all the high-cost antibiotic prescriptions written by these 124, 20 percent of them were written by 24 of these physicians.
 - The heaviest prescribing of these drugs occurred in three areas of the State.

Colorado has regularly developed physician (and patient) profiles to help its review committee determine whether to send an intervention letter to a physician and to help a physician receiving such a letter understand the rationale behind it. The following profile developed for a physician specializing in family practice illustrates this: over a period of 1 year, he prescribed drugs for 50 patients in the review category. Of these patients, 7 were categorized as having a total of 12 "hazard problems" because of their drug therapy, with none of the problems falling in the most serious of the 3 hazard categories. For five of these seven patients, the appropriateness of the drug therapy was questioned because the diagnosis was unclear and for two because the dosages used were contrary to the State's drug use criteria. A graph on the provider profile indicated how this physician compared with his peers (other specialists in family practice) in terms of the number of prescribing problems identified.

- ▶ **Developing Nursing Home Profiles.** In Wisconsin, where about one-third of all Medicaid prescriptions have been for nursing home residents, the State for the past 8 years prepared summary reports of nursing home drug use. The report, sent semi-annually to each nursing home, included a number of measures of drug quality. Each home, which was peer grouped according to the primary medical conditions of its residents, received data comparing it with its peers for each measure. The thrust of the effort was educational. With the information provided, each nursing home could examine how its pattern of drug therapy compared with that in other homes having similar populations and with its own prior practices.

LESSON 5: PRESENT DATA IN WAYS THAT FACILITATE ANALYSIS AND CORRECTIVE ACTION.

The basic data that DUR programs depend on emerge from the screening of claims. This screening process typically focuses on therapeutic categories and/or disease states for which the State has developed DUR criteria. And it is aimed at the identification of problems, such as drug-drug interactions, drug-disease contradiction, and therapeutic duplication. How effectively these problems are then addressed can be greatly influenced by the ways in which the data obtained from the screens are presented to Medicaid agency officials, to the DUR Board, and perhaps most importantly, to the front-line providers who are prescribing and/or dispensing drugs. Effective presentation calls for meaningful context, not just raw numbers. Such context is afforded, for example, when providers' performance is displayed over a period of time and/or is compared to the performance of peers. Such context is also afforded when the number of alerts generated by the screening process is displayed along with the number of claims and patients reviewed for particular drug categories and problem types.

- ▶ **Encouraging Change through Peer Comparisons.** Consider as a case in point a sample summary profile report sent to a Wisconsin nursing home. This report, which is for a facility classified in a "geriatric" peer group, begins with basic background information comparing the facility to others in the peer group in terms of the age of beneficiaries, the level of care they receive, and their main diagnoses. Then it provides drug use information for 47 drugs or categories of drugs, using an * to designate any situation where the facility is greater than 2 standard deviations over the peer group average. Following are a few examples:

PEER COMPARISONS: DRUG USE IN NURSING HOMES			
Drug Group	% of Recipients	\$\$/Recipient	Rx/Recipient
<i>H2 Antagonists</i>			
Your Facility	32.7*	\$238	4.6
Peer Group Average	15.4	\$222	4.2
<i>Concurrent Use of NSAIDs and H2 Antagonists</i>			
Your Facility	10.2	\$433	9.0
Peer Group Average	2.9	\$273	6.3
<i>B-12 Vitamins</i>			
Your Facility	18.1*	\$37	5.6
Peer Group Average	4.0	\$19	2.8

Clearly, in this case, the data display encourages the nursing home leadership to ask why so many more of its residents are on H2 antagonists and B-12 vitamins than residents of other homes. The implication is not that the home should necessarily change its practices, but rather that it should at least confirm for itself the appropriateness of its practices if it does not change them.

Another example of the use of peer group comparisons is the letter that Washington sent to the top 24 users of antibiotic suspensions in treating children with otitis media. Each letter included a table that profiled the physician's prescribing pattern over the course of a year in treating such children and, where possible, comparing it with other physicians in the State. It gave particular attention to a costly drug (we call it Drug X) that was not the State's first drug of choice under its DUR criterion. Following are excerpts from the table sent to one physician:

PEER COMPARISONS: ONE PHYSICIAN'S USE OF HIGH-COST ANTIBIOTICS		
Prescribing Pattern	Your Practice	Peer Average
Ranking amongst prescribers on total number of RX for Drug X	#1	
Number of patients treated under age 8	600	
Number of patients with otitis media	205	
% of otitis to total clients	48%	28%
% of Drug X to total antibiotic drugs	47%	31%
% of Drug X for otitis compared to all antibiotic RX for otitis	73%	58%
Number of times Drug X only was used	137	
Number of times 1 other RX was used before Drug X	20	
Number of times 2 or more RX used before Drug X	6	
Number of times Drug X was used first and then another RX was tried	42	

- ▶ **Assessing the Effects of Prospective DUR Alerts.** Maryland started its on-line pro-DUR program in January 1993. From the beginning, it has produced a monthly report summary of the on-line alerts generated to pharmacies in response to claims they submitted electronically for payment. These reports distinguish "pro-DUR alerts," which represent advisory information to a pharmacy, from "Early Refill Alerts," which represent a claim denial unless the State overrides the denial upon appeal from the pharmacy.

Following is information from Maryland's 1993 annual report to HCFA:

COMPARISONS OVER TIME: CLAIMS/PRO-DUR ALERTS						
Month	Total Claims	Pro-DUR Alerts		Early Refill Alerts		All Alerts as % of Claims
		<i>Total</i>	<i>% Not Filled</i>	<i>Total</i>	<i>% Overridden by State</i>	
<i>Jan</i>	<i>311,593</i>	<i>51,243</i>	<i>41.9</i>	<i>11,421</i>	<i>14.5</i>	<i>20.1</i>
<i>Feb</i>	<i>307,381</i>	<i>46,614</i>	<i>28.5</i>	<i>10,521</i>	<i>14.6</i>	<i>18.6</i>
<i>Mar</i>	<i>397,132</i>	<i>49,387</i>	<i>1.3</i>	<i>15,102</i>	<i>14.3</i>	<i>16.2</i>
<i>Apr</i>	<i>325,182</i>	<i>64,458</i>	<i>23.4</i>	<i>13,621</i>	<i>16.7</i>	<i>24.0</i>
<i>May</i>	<i>325,372</i>	<i>49,986</i>	<i>6.9</i>	<i>16,281</i>	<i>15.8</i>	<i>20.4</i>
<i>Jun</i>	<i>318,442</i>	<i>41,114</i>	<i>1.8</i>	<i>12,757</i>	<i>16.2</i>	<i>16.9</i>
<i>Jul</i>	<i>308,065</i>	<i>42,257</i>	<i>7.9</i>	<i>12,354</i>	<i>17.2</i>	<i>17.7</i>
<i>Aug</i>	<i>384,928</i>	<i>53,594</i>	<i>6.6</i>	<i>16,603</i>	<i>17.9</i>	<i>18.2</i>
<i>Sep</i>	<i>318,691</i>	<i>42,661</i>	<i>2.1</i>	<i>12,682</i>	<i>16.9</i>	<i>17.4</i>
<i>Oct</i>	<i>335,197</i>	<i>43,155</i>	<i>1.7</i>	<i>14,652</i>	<i>15.8</i>	<i>17.2</i>
<i>Nov</i>	<i>408,667</i>	<i>49,212</i>	<i>1.6</i>	<i>16,836</i>	<i>17.5</i>	<i>16.2</i>
<i>Dec</i>	<i>343,636</i>	<i>45,255</i>	<i>1.4</i>	<i>14,705</i>	<i>16.3</i>	<i>17.4</i>

These monthly reports offer valuable perspective to the DUR board and to the Medicaid agency leadership. Most pointedly, they show that early in the first year of implementation pharmacies often responded to the nonmandatory alerts by not filling a prescription; but, by year's end, they had settled into a pattern where they seemed to pay little attention to these alerts. Throughout the year, the level of all alerts--mandatory and nonmandatory--remained quite steady in the 16-17 percent range, as did the level of State overrides of early refill alerts.

LESSON 6: INTERVENE WITH PROVIDERS HAVING QUESTIONABLE PRESCRIBING AND DISPENSING PRACTICES IN WAYS THAT MOTIVATE CHANGE.

The essence of DUR programs is to improve the prescribing and dispensing practices of providers. To do that, the programs must intervene--whether through letters, telephone discussions, or personal visits--in ways that influence providers to change their practices, where necessary, for the long term. Even if States do everything else well, the overall DUR effort can fail if the programs lack an effective intervention strategy. The challenge to State DUR programs has been to adopt approaches that are feasible, yet effective in getting the attention of providers and motivating changes in their prescribing behaviors.

- ▶ **Designing Compelling Letter Interventions.** Sending letters to those with questionable practices is the most common intervention of retrospective DUR programs. It is also one that can be easily dismissed by providers unless States carefully tailor their approach. Montana has personalized its letters to physicians and pharmacists and included specific information about the patient in question (such as a claims-constructed medical history) and suggestions for drug therapy alternatives. The letters bear the signature of the medical director of the Montana/Wyoming Foundation for Medical Care, the Medicare Peer Review Organization, which contracts with the State for the DUR education program.

Some States write physicians not only about particular patients, but also about the physicians' own prescribing practices. Recently, 700 physicians in Pennsylvania received "packets" of information about their prescribing practices for H2 antagonists (see box).

A LETTER INTERVENTION TO PHYSICIANS

The packets sent to Pennsylvania physicians with questionable prescribing for H2 antagonists included:

- o A personalized letter signed by the President of the Pennsylvania Medical Society (PMS);
- o A 12-month profile of the patient's drug and diagnosis history that identifies the primary and secondary therapeutic problems; and cites relevant references in the medical literature;
- o Reprints of relevant articles appearing in recent medical journals including the Statement of the National Institutes of Health Consensus Conference;
- o A one-page, multi-colored flyer for physicians to return to PMS requesting: additional general information, professional consultation with a clinical pharmacist on the PMS staff, or laminated wall charts or pocket cards for each of nine commonly used drug classes including the H2 antagonists.

The letters came from the Pennsylvania Medical Society, which runs the DUR education program for State Medicaid agency. Both agencies believe this arrangement enhances the credibility of the educational interventions with physicians.

Both Montana and Pennsylvania include "RSVP" forms with their intervention letters for the physicians to reply to the drug therapy issue in question. Pennsylvania has sent follow-up letters via certified mail to those physicians not responding to the initial letter. These States have reviewed the immediate RSVPs from the physicians and have followed up with subsequent claims analysis after 6 months, even 1 or 2 years later, to see the extent to which the intervention influenced long-term changes in the physician's prescribing behavior.

- ▶ **Investing in Personal Interventions.** These types of interventions, whether telephone discussions or personal visits, are costly and labor intensive. States use them more selectively than letters.

Both physicians and pharmacists in Illinois can receive telephone calls from the DUR program's consulting pharmacist or physician. In recent months, the State has identified about 50 patient cases a month for this type of intervention. It selects the cases from its retrospective profiling efforts as well as from information generated by its pro-DUR help desk staffed by pharmacists. The cases typically will be those revealing some inconsistencies in the case management of patients; often they will involve patients who have visited multiple pharmacies and/or physicians. The conversations serve as a useful vehicle for obtaining feedback from providers, for clarifying drug therapies, and for conveying the priorities and concerns of the State DUR program.

The Massachusetts DUR program has regularly used face-to-face meetings with providers. It routinely profiles physicians to identify those warranting a more personal educational intervention. The profiling focuses on their prescribing patterns in five therapeutic drug classes, such as anti-ulcer drugs, broad-spectrum antibiotics. The program then compares the individual's prescribing patterns with expected patterns for each drug class. A personal intervention may be chosen for those who deviate from the expected pattern, who see a significant number of Medicaid patients, and whose prescribing patterns suggest that even small changes would significantly improve the quality and cost-effectiveness of their prescribing. Pharmacists working under contract with the DUR program conduct the "counterdetailing" visits. They completed about 100 visits last year.

LESSON 7: FOSTER COMPLIANCE WITH PATIENT COUNSELING REQUIREMENTS.

Counseling patients in the pharmacy when they fill their prescriptions can be an effective way to foster appropriate use of drugs. For that reason, most States have mandated counseling and other pro-DUR requirements for all patients,⁴ not just for Medicaid beneficiaries as the Federal government requires. Yet pharmacists confront many obstacles to providing counseling: insufficient patient information, difficulties communicating with physicians, inadequate clinical pharmacy skills, and limited reimbursement for clinical services.⁵ And State pharmacy boards, which typically monitor compliance as part of their periodic on-site inspections, have difficulty verifying whether pharmacists are actually carrying out the counseling requirements.

- ▶ **Assessing Counseling Practices By "Shopping".** Pharmacy board inspectors in Washington "shopped" pharmacies to assess compliance. Presenting themselves as patients, the inspectors visited 108 randomly selected pharmacies to fill a prescription for an anti-hypertensive drug. Fifty-nine percent of the pharmacies provided these "patients" with either written or verbal information about their prescription. In half the pharmacies, the "patients" also purchased an over-the-counter asthma medication that is contraindicated for concurrent use with the anti-hypertensive drug. In these instances, about one in four pharmacies warned the "patients" against using the two medications together. The pharmacy board used the results as baseline data on counseling practices. The study also spurred the board and the pharmacists' association to work together to identify approaches for ensuring that pharmacists receive further training on counseling requirements and techniques.
- ▶ **Surveying Practices By Mail.** The Virginia DUR program surveyed a random sample of Medicaid pharmacy providers about clinical/cognitive services. The survey was conducted in 1992 before implementation of the on-line, pro-DUR system. Thus, the survey provided useful information to the DUR program about the extent of prospective DUR services being offered across the State and about the obstacles hindering pharmacists from complying more fully with the requirements.

The Colorado DUR program surveyed beneficiaries participating in the Medicaid Primary Care Physician Program. It posed questions concerning the type of pharmacies used by the beneficiaries and the nature of the services provided by pharmacists.

- ▶ **Warning Violators.** Texas has been one of the few States to have taken more punitive actions against pharmacies for violations of counseling requirements. The pharmacy board issued nearly 100 warning notices last year for violations of rules governing prospective DUR. Inspectors noticed these violations during

the periodic, on-site inspections of pharmacies. Though these warnings have not been formal disciplinary actions, the pharmacies had to respond to the pharmacy board within 30 days about how the violations were to be corrected. The board, in turn, has followed up with unannounced visits to some violators to check whether they have come into compliance.

The Texas pharmacy board follows a somewhat different process for those pharmacies for which it receives complaints about lack of counseling. In these instances, the board has sent the pharmacy a certified warning letter reminding the pharmacy/pharmacist of the pro-DUR and counseling rules. A second complaint triggers an investigation, which may involve an undercover operation in which investigators pose as patients. The board has initiated three disciplinary actions. One case resulted in a \$1500 fine; two cases are pending. The board has said it is prepared to take stronger actions ranging from larger fines to possibly license suspensions or revocations.

- ▶ **Sanctioning Pharmacies.** The Iowa pharmacy board formally sanctioned three pharmacies for reasons that include failure to provide effective counseling. It revoked the license of one pharmacy and closed another completely. Each case involved multiple violations of pharmacy and/or controlled substance laws, including a lack of counseling or inappropriate counseling. The board also levied two \$25,000 fines on a single pharmacy. The first fine resulted from dispensing errors and lack of counseling and drug use reviews. The second fine resulted from the pharmacy having violated their probation from the first fine and for other dispensing errors. The pharmacy board has been pursuing sanctions against other pharmacies as well. These cases have come to the board's attention through complaints from consumers and pharmacists.

LESSON 8: EDUCATE PHYSICIANS AND PHARMACISTS PROACTIVELY ABOUT APPROPRIATE PRESCRIBING AND DISPENSING PRACTICES.

State agencies emphasize that DUR programs are intended to be educational in nature. They reinforce this message in their interventions with individual providers identified for some questionable practice. They can convey this message as well through educational outreach to the larger community of practicing physicians and pharmacists. Broadly directed, proactive outreach can alert providers to potential problems in drug therapy, provide them with information on how to address those problems, and, in so doing, have significant preventive value.

- ▶ **Mailing Special Messages.** Kentucky has been developing "Therapeutic Algorithms" with input from Medicaid physicians and pharmacists, academics, and professional organizations across the State. It recently sent to all Medicaid providers the first algorithm for treating acute urinary tract infections. The State views this process as an educational approach that can improve patient care and reduce Medicaid costs; use of the algorithms is not mandatory. Topics for these algorithms focus on diseases that affect many Medicaid beneficiaries, cost the program substantial sums of money, and reflect considerable variation in treatment approaches. Others will deal with pain management, otitis media, and hyperlipidemia. Outcome analyses will assess the effectiveness of this approach.

Medicaid providers in Colorado received guidelines for evaluating and treating insomnia through the Medicaid Pharmacy Newsletter. The guideline described various behavior modification techniques, types of benzodiazepine drugs and their characteristics, and a process for discontinuing hypnotic therapy with a 6-week schedule for tapering dosages.

Other States, including Virginia, Washington, and Pennsylvania, make regular use of newsletters/journals of the professional associations or the State Medicaid agencies themselves to make educational information broadly available to providers. These approaches target only Medicaid providers in some instances; in others, the publications reach a broader audience of associations' members.

- ▶ **Training and Consulting for Providers.** Several States have been targeting special groups of providers for specific training on drug therapy issues.
 - The Pennsylvania Medical Society, under contract with the Medicaid agency, has been leading seminars for hospital staff in those areas of the State, such as Pittsburgh and Philadelphia, that have many Medicaid beneficiaries. It has also sponsored free, day-long seminars for

physicians on prescribing therapies for minority patients. Some training activities are offered with Continuing Medical Education credits as incentives to physicians to participate.

- Vermont has conducted special seminars for the residents in training at the University of Vermont Medical Center. The retrospective reviews were generating many alerts that the DUR staff were able to associate with the hospital's residents. A DUR board member, who is also a staff pharmacist at the medical school, collects these alerts and periodically discusses them with the students.
 - Wisconsin has trained pharmacists and nurses in long-term care facilities about identification and treatment of depression in the elderly.
 - Pennsylvania operates a toll-free telephone line at the Medical Society for inquiries about drug therapies from providers. A clinical pharmacist is available for consultation as well.
- ▶ **Connecting Through the Information Superhighway.** At least two States are examining the potential for reaching large numbers of providers through automated information systems.

Washington has long used an automated bulletin board system for communicating with Medicaid physicians; more recently it has been available to pharmacists. Listings include policy memoranda, billing instructions, physician provider numbers, the Medicaid drug formulary, and information on new drug products. Review criteria may well be added after they are updated in 1995.

Iowa is exploring ways to tap into various telecommunications systems available in the State. A state-wide, fiber optic network, capable of transporting interactive, two-way audio, video, and data signals, is now up and running for various educational purposes. And the University of Iowa, too, has a telemedicine capability that may be a cost-effective mechanism useful to the DUR program for sharing information with physicians and pharmacists across the State.

LESSON 9: ESTABLISH ONGOING RESEARCH EFFORTS TO HELP GUIDE THE DUR PROGRAM.

A relatively limited knowledge base is available to help guide DUR boards and State officials. Thus, it is very important for States to incorporate applied research efforts into their DUR programs to help them operate efficiently and effectively. Ideally, results from research based on operating experiences could (1) inform decisions about criteria, screening strategies, interventions, and the like, and (2) offer opportunities for disseminating and discussing the results with the professional communities.

- ▶ **Evaluating Screening Criteria.** Maryland uses its "DUR Analytic Reports" to assess the effects of its pro-DUR screening criteria. These reports focus on the frequency of criteria exceptions over a 10-13 month period. First the exceptions are aggregated by drug class (e.g., H2-receptor antagonists) and then, within each drug class, criteria element (e.g., therapeutic duplication, adverse drug-drug interactions, etc.). The data are presented in tables and graphs together with a narrative that highlights concerns and recommendations for action (see box for excerpts from one report).

DUR ANALYTIC REPORT NOV 93 - AUG 94		ANGIOTENSIN CONVERTING ENZYME INHIBITORS (ACEIs)		
Criteria		Total # Rxs	Total # Exceptions	Exceptions per 100 Rx
Drug-drug interaction <i>lithium</i>	all ACEIs	94,831	2,096	2.21
	benazepril	2,135	103	4.82
Drug-drug interaction <i>K+ sparing diuretics</i>	all ACEIs	94,831	1,119	1.18
	captopril	28,511	633	2.22

RECOMMENDATIONS:

- o The criteria "K+ supplements without K+ wasting diuretics" is not implementable by prospective DUR. A message could be added to a "K+ supplement" criteria that states "check to be sure patient is also taking a K+ wasting diuretic" or, alternatively, this criteria element could be "switched off."
- o Finally, benazepril occurs as an outlier in virtually every criteria element (*Note: not all criteria included here*) analyzed...All benzepiril criteria should be checked to ensure correct implementation and to determine if there is something specific about benazepril that would make its use unusual when compared to other ACE inhibitors.

The DUR board relies on these "Analytic Reports" when deciding whether or not to change the criteria, whether to modify their implementation, or whether to pursue educational interventions with providers.

- ▶ **Assessing Alerts by Practice Setting.** Iowa's Drake University used DUR data to examine therapeutic screen failures by geographic location of the prescriber. The profiles from a group of prescribers whose drug regimens failed the computerized therapeutic and utilization criteria screens were compared with a control group of prescribers whose profiles passed the screens. The study concluded that prescribers located in more rural settings were more likely to fail the criteria screens and that patients in nursing homes were more likely to receive inappropriate prescriptions.
- ▶ **Identifying Physician Preferences.** The Pennsylvania Medical Society, under contract with the Medicaid agency to run the educational component of the DUR program, spent its first year researching the views of practicing physicians across the State. It conducted nearly a dozen focus groups and surveyed nearly 3,000 randomly selected physicians. The Society asked physicians for suggestions and ideas about how it could best convey information about appropriate drug therapies, how it could intervene effectively with them, and which topics and therapies were of most interest to them. This research informed the strategies developed for the DUR educational program.
- ▶ **Examining the Effectiveness of Interventions.** One research project in Colorado focussed on approaches for improving physicians' awareness of the costs of various nonsteroidal anti-inflammatory drugs (NSAIDs), commonly used for treating arthritis. The goal was to increase the use of the low-cost NSAIDs in uncomplicated cases. The intervention group of physicians received letters together with individual practice profiles, comparison data with peers, and cost information for the various NSAIDs. The control group of physicians received no information on their NSAID prescribing. The follow-up analysis indicated that the intervention group reduced the cost of their NSAID therapy more than did the control group. Researchers concluded that receiving detailed information was a significant influence in changing physicians' prescribing practices.

Wisconsin evaluated the effectiveness of letters with different provider groups in reducing the use of an antiplatelet agent. Researchers sent letters to physicians only in one group, to pharmacists only in a second group, and to both pharmacists and physicians in a third group. Post-intervention analysis compared outcomes among these groups and with a control group who had no intervention. The research confirmed that sending letters to both physicians and pharmacists was significantly more effective in reducing use of the antiplatelet agent than sending letters only to physicians or to pharmacists.

MAJOR CHALLENGES FACING STATE DUR PROGRAMS

One of the often-mentioned tenets of American federalism is that State governments can serve as laboratories for experimentation. This certainly has been the case for State DUR programs. Moving ahead in largely uncharted territory, States have been crafting many different approaches to DUR and have been learning from their experience. Through this report, we attempt to increase awareness of some of the major lessons they have learned.

We can not close, however, without also discussing some concerns we have identified about the current state of DUR programs. In so doing, we draw on our considerable experience in examining DUR issues over many years and, more specifically, on observations we made and comments we heard during our inquiry for this study. We raised these concerns at a recently held symposium on Medicaid DUR issues that involved representatives from most States and received considerable feedback reinforcing their importance.⁶ They present challenges that, if not addressed adequately by State and Federal leadership, could undermine the effectiveness of DUR programs in the years ahead. We present them here, in the form of questions, with the intent to stimulate thinking about how they might be constructively addressed.

Privacy safeguards.

- ▶ *Do the programs give adequate attention to privacy safeguards?*

The widespread use of electronic claims data by Medicaid DUR programs raises major questions concerning the collection, management, and disclosure of such data. How much and what kind of data can be collected on beneficiaries? Who can have access to such data and under what conditions? What safeguards are necessary to prevent unauthorized access? Such questions were beginning to gain major attention in 1989 as the Federal government was preparing to implement the (subsequently terminated) Medicare DUR program.⁷ As Medicaid DUR programs gain momentum and visibility, the very same questions are likely to surface.⁸ And many do not seem to be adequately prepared. The kind of controversy that can easily arise through the development of electronic data bases is illustrated in a recent **Boston Globe** story with the headline: "HMO puts confidential records on-line: Critics say computer file-keeping breaches privacy of mental health patients."⁹

Protection of poor performers.

- ▶ *Does the educational focus of the programs unnecessarily inhibit efforts to protect beneficiaries from poorly performing providers?*

State DUR programs stress what they can do for providers, not to them. This approach, they hold, is more likely to generate improved performance than is a punitive one. Accordingly, when they identify questionable prescribing or dispensing practices, their subsequent contact with the provider is almost always strictly informational, with no follow-up action actually required of the provider. On rare occasions, when a particularly egregious practice is identified, the DUR program will refer information on the provider to a State medical or pharmacy board or to the Surveillance and Utilization Review component of the Medicaid agency.

But what happens when serious questions are raised about a provider's knowledge base and/or practice skills, but they are not serious enough to call for referral for possible disciplinary action? The DUR programs appear to devote little attention to crafting responses tailored to such situations. They could, for instance, require a provider to take certain remedial actions, such as participating and satisfactorily completing a course addressing proper prescribing or dispensing practices. This kind-of mid-range response, which is essentially educational in nature, would help protect patients from poor care and, from the providers' perspective, would still be educational in nature.

Education of patients.

- ▶ *Are the programs sufficiently focused on patient education?*

In a far-reaching survey on the future of medicine, *The Economist* recently concluded that patients are beginning to assume control over the health care system.¹⁰ As medical and information technology continue to develop, the traditional authority of health care professionals is diminishing and patients are gaining influence over decisions concerning their medical care. State DUR programs, however, pay little attention to this significant transformation. Their educational efforts, in accord with Federal direction, focus almost strictly on physicians /and to a lesser degree on pharmacists. The challenge of helping patients become more informed participants in their own drug therapy is seldom addressed. The time seems to be right to examine this situation and to search for ways of incorporating patient education as an important component of DUR programs.

Dependence on vendors.

- ▶ *Are the programs too dependent on the vendors serving them?*

The intent here is not to dismiss the contributions of vendors carrying out contracts with State DUR programs. They provide valuable expertise, much of it of a highly technical nature, to nearly all aspects of the DUR programs. But an outside observer can not help but notice that often the State agencies lack the internal expertise to ensure that the work of the vendors is being tailored to the particular needs of the States. As a result, important decisions about the development and use of criteria, about the nature and scope of interventions, and about the thrust of educational

initiatives are sometimes being left to vendors. In some States, the DUR boards seem to provide some of this leadership, but typically their participation is too infrequent (often only quarterly meetings) to play more than an advisory role.

Problems with Medicaid claims data.

- ▶ *Do inaccuracies and omissions in the Medicaid claims data bases serve as a significant constraint to the programs?*

Unquestionably, problems with the accuracy and completeness of data often limit the effectiveness of DUR programs. We heard reference to them in just about every State we contacted. How extensive and consequential the problems are, however, is unclear. We did hear that one large State has not been sending out any intervention letters to providers identified through its retrospective screening process because of concerns about the accuracy of the claims data being screened. For the most part, the concerns that State officials cited about accuracy focused on improperly coded diagnostic information. But they also pointed to an array of other inaccuracies concerning data provided on such important matters as provider number, provider specialty, drug code, and Drug Enforcement Administration number. In some cases, such inaccuracies existed alongside significant omissions in the claims data submitted. For instance, one State reported that about one-third of its pharmacy claims being submitted were missing a physician provider number.¹¹

Validity of cost savings estimates.

- ▶ *Are the programs claiming cost savings that rest on weak foundations?*

Documenting cost savings is an essential element of DUR programs. The HCFA, in accord with congressional requirements, calls for cost savings to be included in the States' annual DUR reports. More significantly perhaps, State governments, in their quest to contain escalating Medicaid costs, look to the programs to contribute to cost savings and to document their success in doing so. Other than on the most obvious kinds of matters, such as eliminating a duplicate prescription, the job of developing sound estimates, particularly with little data available linking DUR interventions to medical outcomes, is highly complex and resource intensive. Yet, this does not lessen the imperative to arrive at such estimates. What happens, therefore, is that States often claim savings associated with their prospective DUR alerts to pharmacists or their retrospective interventions to physicians that fail to take into account indirect or deferred costs associated with a reversed drug claim or a changed prescribing practice. The HCFA has recognized the vulnerability of this situation and has helped to address it by supporting the development and distribution of a set of guidelines on estimating the impact of DUR efforts.¹² But the situation remains one that can offer misleading indications of the impact of DUR programs.

Balance between cost and quality.

- ▶ *Are the cost-saving and quality-of-care objectives of the programs in balance?*

Saving costs is a vital component of DUR programs. So, too, is improving drug therapy. It is certainly possible that DUR initiatives can help contain costs as they improve drug therapy. Many appear to be developed with this intention. Yet, in devising DUR efforts, choices are made that weight the emphasis given to the respective objectives. These are reflected in decisions on what drug use criteria to develop, what ones to apply in the screening process and how often, and what degree of specificity to use in applying the criteria. What may seem to be mundane decisions, often shrouded in the complexities of computer algorithms, can, in fact, involve significant choices on DUR objectives. Given the cost pressures noted earlier, the cost-saving objective surely looms large in this process. The concern here is not necessarily that quality will be sacrificed. We saw no such indications. More possible, perhaps, is that providers and patients will come to perceive DUR programs primarily as mechanisms to contain costs and only secondarily to foster more effective use of prescription drugs. As an example, prospective DUR programs that trigger alert rates of close to 20 percent for pharmacy claims can clearly contribute to this perception.

Implications of managed care.

- ▶ *Are States developing a DUR infrastructure that will become increasingly irrelevant as Medicaid managed care enrollment escalates?*

Medicaid managed care enrollment is rising sharply. From 9.5 percent of the eligible population in June 1991, it increased to 23.2 percent in June 1994. Given the high level of interest in managed care and the Federal waivers facilitating Medicaid enrollment in managed care, the proportion almost certainly will continue to rise; by the year 2000 it could reach about 50 percent of the eligible population.¹³

Thus far, State DUR programs have given little attention to the implications of this trend for their own efforts. But the implications are profound and warrant immediate consideration. Many of the managed care plans include prescription drug coverage. As Medicaid beneficiaries join such plans, they are, in effect, lost to the DUR program, with the plan assuming the responsibility (and risk) for cost-effective drug therapy. This development could, in fact, allow for improved drug utilization review, more effectively tied in with overall medical care. Managed care, in short, is not necessarily in conflict with good DUR. But State DUR programs appear to have little understanding of the nature and scope of the drug utilization review that occurs under the auspices of managed care organizations (MCOs). Some States are moving in the direction of asking MCOs for drug encounter data. But such efforts have barely begun and here, too, there is little understanding of whether they are likely to be effective.

APPENDIX A

NOTES

1. Public Law 101-508, November 5, 1990, (Omnibus Budget Reconciliation Act of 1990).
2. Our studies on pharmacy issues include:

Medicare Drug Utilization Review, (OAI-01-88-00980), April 1989.

Privacy Implications of the Medicare Prescription Drug Benefit's Electronic Claims Processing System: A Management Advisory Report, (OAI-01-89-89170), April 1989.

Physician Drug Dispensing: An Overview of State Regulation, (OAI-01-88-00590), May 1989.

State Discipline of Pharmacists, (OAI-01-89-89020), July 1990.

Symposium on Drug Utilization Review Issues: Proceedings, (HHS-100-89-0021), August 1990.

Symposium on Drug Utilization Review Issues: Summary Report, (OEI-01-89-89010), August 1990.

The Clinical Role of the Community Pharmacist, (OEI-01-89-89160), November 1990.

The Clinical Role of the Community Pharmacist: Case Studies, (OEI-01-89-89161), November 1990.

Promotion of Prescription Drugs Through Payments and Gifts, (OEI-01-90-00480), August 1991.

Point-of-Service Claims Management Systems for Medicaid, (OEI-01-91-00820), May 1992.

Prescription Drug Advertisements in Medical Journals, (OEI-01-90-00482), June 1992.

Prescription Drug Promotion Involving Payments and Gifts: Physicians' Perspectives, (OEI-01-90-00481), July 1992.

3. In a 1994 report, Health Systems Research pointed out the considerable variation that exists in the scope, detail, and relationship of DUR criteria to the scientific literature. It also noted that State officials and DUR board members often "know very little about the quality of the DUR criteria used in prospective and retrospective DUR interventions." See Health Systems Research, *Recommendations for Improving the Quality and Effectiveness of State Medicaid Drug Utilization Review Activities*, a paper submitted to the Office of Medicaid Management, Health Care Financing Administration, February 28, 1995.
4. National Association of Boards of Pharmacy, *Patient Counseling Requirements*, Park Ridge, IL, 1993.
5. See OIG, *The Clinical Role of the Community Pharmacist*.
6. American Drug Utilization Review Symposium, San Antonio, Texas, February 16-19, 1995.
7. We addressed raised and addressed these questions in an earlier report. See OIG, *Privacy Implications of the Medicare Prescription Drug Benefit's Electronic Claims Processing System: A Management Advisory Report*.
8. Section 456.703 (h) of 42 CFR 456 calls for States to establish policies on confidentiality of patient-related data that are consistent with Federal confidentiality requirements, State pharmacy practice acts, and State pharmacy board guidelines. And Section 5350 of the State Medicaid Manual issued by the Federal government stipulates that the "use or disclosure of information concerning applicants and recipients is restricted to purposes directed related to administration of the title XIX State plan." These instructions provide some guidance to States, but still call for much interpretation as States rely increasingly on electronic claims information.
9. **Boston Globe**, March 7, 1995. The visibility generated by the newspaper coverage led the medical director of the HMO cited to offer the following comment: "We may well need to change our guardrail around patient confidentiality. Regardless of what our doctors think they need to know, we have to pay attention to what our patients want them to know." **Boston Globe**, 9 March 1995.
10. "A Survey of the Future of Medicine," **The Economist**, 19 March 1994, pp. 1-18.

11. An early 1994 review of State DUR programs conducted for HCFA also raised questions about the quality of data available for DUR programs. Its focus, however, was on the quality of data available to evaluate the performance of the programs. See Elizabeth Donnelly Appel, Health Systems Research, **Recommendations for Improving the Quality and Effectiveness of State Medicaid Drug Utilization Review Activities**, February 28, 1994, p. 5.
12. David Zimmerman, Ted Collins, Earlene Lipowski, David Kreling, and Joseph B. Wiederholt (Consultants to Shepard Patterson, Inc.), **Guidelines for Estimating the Impact of Medicaid DUR**, (Contract #500-93-0032), August 1984.
13. Lee Partridge, "Medicaid and Managed Care," *Washington Memo*, American Public Welfare Association, February 1995, pp. 13-20.